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09/980,573	02/06/2002	Harald Genger	22054	5984

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/980,573

Applicant(s)

GENGER ET AL.

Examiner

Jonathan ML Foreman

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-- Th MAILING DATE of this communication appears on th cover sh et with the correspondence addr ss --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7. 6) ☐ Other: \_\_\_\_

### ***Information Disclosure Statement***

The information disclosure statement filed 1/25/02 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

### ***Specification***

1. The disclosure is objected to because of the following informalities: There are no headings such as "Background", "Brief Description of the Drawings", etc. separating the different sections of the disclosure. Additionally, page 8, line 28, states "Figure 3b", however the disclosure appears to be directed at Figure 3a.

Appropriate correction is required.

2. Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper form, or rewrite the claim(s) in independent form. Claim 13 is the same as claim 3.

### ***Drawings***

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the stiffening element/device must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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*Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 8 – 11 and 14 – 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to claim 8, it is unclear what configuration is meant by the phrase, “mounted into an application surface yielding in a substantially perpendicular direction”.

6. Claim 9 recites the limitation “the electrode elements” in line 2. Claims 10 and 11 recite the limitation “the signal processing device” in line 2. Claims 14, 15 and 16 recite the limitation “the mask member” in line 2. There is insufficient antecedent basis for these limitations in the claims.

Although unclear, the claims have been reviewed by the examiner as best understood at this time in order to continue with the examination.

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 5 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by DE 3927038 A1 to Hofer.

In reference to claims 1, 2, 5 and 15, Hofer discloses a device (Figure 1) with an electrode device (3) applied to the forehead region of the patient, where the electrode device is arranged on a forehead support element (5) that co-operates with a breathing mask device (1) in a way that the position of the electrode device is established in conjunction with the application position of the breathing mask device. The forehead support element (5) is coupled to the mask device and is integral with the mask. A stiffening element (2) couples together the forehead support element and the breathing mask device.

9. Claims 1, 2, 4, 6, 7, 9, 11, 15, 17 and 19 are rejected under 35 U.S.C. 102(e3) as being anticipated by U.S. Patent No. 6,199,550 to Wiesmann et al.

In reference to claims 1, 2, 4, 6, 7, 9, 11 and 15, Wiesmann et al. discloses a device (Figure 3) with an electrode device applied to the forehead region of the patient (Col. 5, lines 25 – 27), where the electrode device is arranged on a forehead support element (50) that co-operates with a breathing mask device in a way that the position of the electrode device is established in conjunction with the application position of the breathing mask device. The forehead support element (50) is coupled to the mask device and is integral with the mask. The forehead support element is formed in one piece with a mask base member. The electrode device has three electrode elements (20, 22, 70). The electrode elements are coupled to a signal processing device (Col. 5, lines 62 – 67).

In reference to claims 17 and 19, Wiesmann et al. discloses an electrode device (20, 22, 70), a measuring circuit arrangement for producing data in accordance with the electrical potentials (Col. 5, lines 62 – 67) detected by the electrode device, characterized in that the circuit is partially integrated into a forehead support element (Col. 5, lines 25 – 27), and there is a signal transmission device for cord-less transmission of the data produced by the measuring circuit and a data recording device (Col. 13, line 55 – Col. 14, line 33).

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10. Claims 17, 18 and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,171,258 to Karakasoglu et al.

In reference to claims 17, 18, and 19, Karakasoglu et al. discloses an electrode device (Col. 5, lines 4 – 17), a measuring circuit arrangement for producing data in accordance with the electrical potentials detected by the electrode device, characterized in that the circuit is partially integrated into a forehead support element (Col. 2, lines 27 – 31), and there is a signal transmission device for cord-less transmission of the data produced by the measuring circuit (Col. 4, lines 58 – 63). Karakasoglu et al. discloses a measurement data recording device for recording measurement data produced by the measuring circuit arrangement. Karakasoglu et al. discloses a data compression device for forwarding compressed data (Col. 5, line 57 – Col. 6, line 27).

11. Claims 17, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,381,481 to Levendowski et al.

In reference to claims 17, 19, and 20, Levendowski et al. discloses an electrode device (Col. 10, lines 25 – 30), a measuring circuit arrangement (178, 182, 194) for producing data in accordance with the electrical potentials detected by the electrode device, characterized in that the circuit is partially integrated into a forehead support element (Col. 10, line 64 – Col. 11, line 4), and there is a signal transmission device (184) for cord-less transmission of the data produced by the measuring circuit. Levendowski et al. discloses a measurement data recording device for recording measurement data produced by the measuring circuit arrangement. The data recording device is formed by an approximately postage stamp-size memory card element (Flash Memory) that is releasably fitted (Col. 15, line 56 – Col. 16, line 9).

*Claim Rejections - 35 USC § 103*

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1 – 7 and 9 -16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,532,961 to Kwok et al. in view of U.S. Patent No. 6,171,258 to Karakasoglu et al.

In reference to claims 1 – 7 and 9 - 16, Kwok et al. discloses a mask member (Figure 1) engages over the nose region of a patient, a sealing device (19) for sealing off an inner region of the mask with respect to the ambient atmosphere, and a forehead support element (25) for supporting the mask member in the forehead region of the patent. The position of forehead support element is established in conjunction with the position of the mask device. The forehead support element is coupled to the mask device and integral with the mask device (Col. 4, lines 45 – 47). The forehead support material and the mask member are formed of an elastomer material (Col. 4, lines 47 – 49; Col. 5, lines 13 – 17; Col. 6, lines 23 – 25). Kwok et al. discloses a stiffening element (12) that couples the forehead support element and the mask device and that allows the mask member and the forehead support to adapt to the individual contour of the face of the patient (Figures 4 – 7). However, Kwok et al. fails to disclose the forehead support element having an electrode device for detecting brain-electrical potentials of a patient. Karakasoglu et al. discloses a forehead support element having three electrode elements for detecting brain-electrical potentials of a patient (Col. 5, lines 18 – 22). It would have been obvious to one having ordinary skill in the art to modify the forehead support device as disclosed by Kwok et al. to include an electrode device for detecting

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brain-electrical potentials as taught by Karakasoglu et al. in order to diagnose sleep disorders and to ascertain sleep staging of a patient (Col. 5, lines 1 – 6).

***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,777,963 to McKenna, U.S. Patent No. 4,802,485 to Bowers et al. and U.S. Patent No. 6,272,378 to Baumgart-Schmitt.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703)-305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703)308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703)-872-9306 for regular communications and (703)-872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-0858.

  
JMLF

October 28, 2003

  
MAX F. HINDENBURG  
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